



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Public Health Service

Food and Drug Administration
College Park, Maryland

JUL 27 2003

WARNING LETTER
ONPLDS 03-03

BY CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mickey Miller, President
Flowers Baking Company of Thomasville, Inc.
300 South Madison Street
Thomasville, Georgia 31792

Dear Mr. Miller:

The Food and Drug Administration (FDA) has reviewed the label for Nature's Own Reduced Carbohydrate Premium Wheat bread. As a result of our review, we have determined that this label causes the product to violate the Federal Food, Drug, and Cosmetic Act (the Act) and implementing regulations in Title 21 of the Code of Federal Regulations. The specific violations relate to misbranding and are explained below.

First, this product is misbranded under section 403(r)(1)(A) of the Act (21 USC 343(r)(1)(A)) because its label bears the nutrient content claim "Reduced Carbohydrate," which is not a term defined by FDA by regulation (*see* 21 USC 343(r)(2)(A)(i)). Similarly, the claims "Only 7 Grams of Carbohydrates Per Slice" and "50% Less Carbohydrates Than Regular Bread" are also nutrient content claims in violation of the Act. These claims are unlawful because they implicitly characterize a level of carbohydrate in this bread product and are not made in accordance with the regulations in 21 CFR Part 101, Subpart D (*see* 21 USC 403(r)(2)(A)(i); 21 CFR 101.13(b)). Although FDA has not established regulations for the types of claims set out above for carbohydrates, the regulations permit statements that do not in any way implicitly characterize the level of a nutrient in a food and are not false or misleading in any respect (*see* 21 CFR 101.13(i)(3)). For example, statements such as "100 calories" or "5 grams of fat" or, in this instance, "7 grams of carbohydrate," are permissible labeling claims.

Second, Nature's Own Reduced Carbohydrate Premium Wheat bread is also misbranded because its label bears the claim "An Excellent Source of Fiber," which is not made in accordance with 21 CFR 101.54(b). Section 101.54(b) permits an "excellent source of fiber" claim on the label or in the labeling of foods provided that the food contains 20% or more of the Daily Reference Value (DRV) for fiber per reference amount customarily consumed (RACC). The DRV for fiber is 25 grams (*see* 21 CFR 101.9(c)(9)) and the RACC for bread is 50 grams (*see* 21 CFR 101.12, Table II). Thus, in order for a product to bear an "excellent source of fiber" claim, it must contain at least 5 grams of fiber per 50 gram serving. The nutrition information for this bread, however, states that one 28 gram serving contains only two grams of fiber. This amount fails to meet the requisite standard established by 21 CFR 101.54(b) to qualify for an "excellent source of fiber" claim.

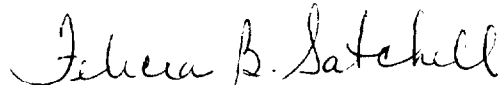
Finally, this product's labeling violates FDA's regulations because it bears the claim "2 Grams of Soy Protein Per Slice" without including the Percent Daily Value for protein in the nutrition information, as required by 21 CFR 101.9(c)(7)(i).

The above violations are not meant to be an all-inclusive list of deficiencies for the labeling of Nature's Own Reduced Carbohydrate Premium Wheat bread or any other products your firm manufactures or labels. It is your responsibility to ensure that all of your products are labeled in compliance with applicable statutes and regulations. You should take prompt action to correct these deviations and prevent their future recurrence. Failure to make prompt corrections could result in regulatory action without further notice. Possible actions include seizure and/or injunction.

Please notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken or plan to take to correct the noted violations. Copies of revised labels for the product should be submitted. If corrective actions cannot be completed within 15 working days, state the reason for delay and the time within which corrections will be completed.

You should direct your written reply to me at the Food and Drug Administration, Center for Food Safety and Applied Nutrition, Office of Nutritional Products, Labeling and Dietary Supplements (HFS-820), 5100 Paint Branch Parkway, College Park, Maryland 20740.

Sincerely yours,



Felicia B. Satchell
Director

Division of Food Labeling
and Standards

Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Copy to:
Edward Logue, Manufacturing Manager
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